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EXAMINER	
FOSTER, CHRISTINE E	
ART UNIT	**PAPER NUMBER**
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/719,735	MINDEN, JONATHAN SAMUEL	
	Examiner	**Art Unit**	
	Christine Foster	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *10-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 25-38* is/are rejected.

7)☒ Claim(s) *5-6, 8-9, 27-28 and 36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/21/08*.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Please note that the Examiner in this application has changed. The new Examiner, Christine Foster, may be reached at 571-272-8786.

Amendment Entry

1. Applicant's amendment, filed 12/20/2007, is acknowledged and has been entered. Claims 1-9 and 25-38 were amended. Claims 1-38 are pending in the application, with claims 10-24 currently withdrawn. Claims 1-9 and 25-38 are subject to examination below.

Priority

2. The present application was filed on 11/21/2003 and claims benefit under 35 U.S.C. 119(e) to provisional application No. 60/428,560, filed 11/22/2002.

Objections/ Rejections Withdrawn

3. The rejections of claims 1-3, 5-9, 25 and 27-38 under §102(e) as being anticipated by Shen & Heiati et al., and of claims 1-9 and 25-38 under §103 as being unpatentable over Shen & Heiati et al., have been withdrawn in response to Applicant's persuasive arguments (Reply, pages 8-13).

Claim Objections

4. Claims 5-6, 8-9, 27-28, 30 and 36 are objected to because of the following informalities:

5. It appears that in claims 5-6, 27, and 36 Applicant intends to recite Markush-type claims, but the claim language does not make this clear. For example, the language in claim 5 "the maleic anhydride compound comprising a dialkyl maleic anhydride and derivatives thereof" is presumed by the Examiner to mean that the maleic anhydride compound comprises either a dialkyl maleic anhydride or derivatives thereof. However, the claim language is confusing and could be misinterpreted as meaning that the maleic anhydride compound includes both a dialkyl maleic anhydride as well as derivatives thereof. Clarification is needed. See MPEP 2173.05(h) for examples of acceptable forms of alternative expression.

6. Claims 8-9 refer to "the biomolecule to which maleic anhydride compound is bound". It appears that Applicant intends to refer back to the "maleic anhydride compound" recited in claim 1. It is suggested that the dependent claims refer to "<u>the</u> maleic anhydride compound" in order to make this clear.

In addition, claim 1 (from which claims 8-9 depend) does not state that the maleic anhydride compound <u>is</u> bound to a biomolecule, only that it includes an exposed carbonyl for this purpose. It is presumed that the claimed device does not actually include the bound biomolecule, as reaction of maleic anhydride with an amine-containing biomolecule (such as a protein) hydrolyzes the maleic anhydride (see instant Figure 2). Therefore, it appears that claims 8-9 are intended to define the biomolecules that the maleic anhydride compound is *capable of binding*. As written, however, the claims may present confusion as they could be misinterpreted as meaning that the device includes the biomolecule already bound to the maleic anhydride compound. Clarification is requested.

7. Claim 30 recites the limitation "the maleic anhydride" in part (c). However, part (b) recites “maleic anhydride compounds” in the plural. Although such compounds can be envisaged to include maleic anhydride *per se*, the recitation of “the maleic anhydride” in the singular may present confusion since multiple maleic anhydride compounds are invoked earlier in the claim.

8. Similarly, claim 28 recites “said dialkyl maleic anhydride compounds” in the plural, while independent claim 25 refers to "a dialkyl maleic anhydride compound" in the singular.

Appropriate correction is required.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 5-6, 27, 30, and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claims 5-6, 27, and 36 are indefinite in reciting that the maleic anhydride compound comprises “**derivatives**” of dialkyl maleic anhydride. The specification mentions “derivatives” of 2,3 diethyl maleic anhydride on page 8, lines 9-11 but does not provide a specific or limiting definition for this term. The metes and bounds of the claims are unclear because it is not apparent in what sense or by what process(es) such “derivatives” are related to the dialkyl maleic anhydrides from which they are derived. Further, it is not clear what types of modifications, substituents, etc., or the extent of same, would be permitted for a compound to still be considered a “derivative” of a given dialkyl maleic anhydride.

12. Claim 30 is recites a device comprising a desired biomolecule "forming a reversible amide linkage with the maleic anhydride". This language renders the claim indefinite because is unclear whether Applicant intends that the biomolecule is present as part of the claimed device, linked to the maleic anhydride, or alternatively whether the recitation of the biomolecule refers to the intended use of the device in separation. In the former case, is unclear how the biomolecule could in fact be reversibly linked to maleic anhydride *per se*, since biomolecule binding hydrolyzes the maleic anhydride ring (see Figure 2). Clarification is needed as to whether the biomolecule is actually part of the claimed device, and if so, how it is being provided (e.g., bound to the solid substrate or as a separate component).

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-3, 5-6, 8-9, 31, 34, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Pierce Chemical Co. ("Reacti-Bind™ Maleic Anhydride Activated Polystyrene Plates" Immunotechnology Catalog & Handbook, 1992, page 54).

Pierce teaches a substrate having a surface (polystyrene microtiter plates) bound to a maleic anhydride compound (see entire selection). As depicted in the figure, the maleic anhydride compound is attached to the plate via a linker at a molecular 2 or 3 position (depending on nomenclature) of the maleic anhydride. Pierce further teaches that the maleic

anhydride-activated plates are capable of covalently binding to amine-containing biomolecules such as proteins at pH ≥7.2 (i.e., "selected pH conditions", see right column). As disclosed in the instant specification, the Reacti-Bind™ Maleic Anhydride Activated Polystyrene Plates are capable of reversible binding (specification, page 2, lines 9-14). As such, the plates would be capable of performing the intended use of *in vitro* separation as recited in the preambles of claims 1, 30, and 38.

Pierce does not explicitly state that maleic anhydride is covalently bound to the polystyrene plates. However, covalent attachment is suggested by the depiction in the figure of Pierce, where the linker attached to the 2 or 3 position of the maleic anhydride is shown protruding into the surface of the polystyrene plate (note similarity to instant Figure 2). Because the product of Pierce appears to be substantially identical to that claimed, it is Applicant's burden to establish that the prior art product does not necessarily or inherently involve covalent attachment (see MPEP 2112).

With respect to claims 5-6, as discussed above these claims are presumed to recite that the maleic compound is a dialkyl maleic anhydride or a derivative thereof. Absent a specific or limiting definition in the specification for "derivatives", the maleic anhydride compound of Pierce would be considered a "derivative" of dialkyl maleic anhydride.

With respect to claims 8-9, 31, and 34, Pierce teaches covalent attachment to large and small amine-containing molecules, including proteins, via an exposed carbonyl of the maleic anhydride (see entire selection, in particular the figure).

15. Claims 25, 27-29, and 31-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Sundberg et al. (US 5,624,711).

Sundberg et al. teach a device ("derivatized support") having a solid surface such as glass (abstract; column 1, line 64 to column 2, line 37; column 5, line 66 to column 6, line 10; column 11, lines 20-40). Polymers may be covalently attached to the surface of the support (column 5, lines 25-35), including poly(ethylene/maleic anhydride), which reads on the instantly recited dialkyl maleic anhydride compound (see Figure 9b and column 15, lines 12-20 and line 53 to column 16, line 11).

With respect to the recitation in the preambles of claims 25 and 35 that the device is "for the *in vitro* separation of biomolecules from a solution", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the polymer-coated device of Sundberg et al. would be capable of being used for *in vitro* separation of biomolecules because, like the disclosed devices, it contains exposed maleic anhydride moieties that would necessarily also be capable of reversible covalent reaction with proteins and other biomolecules having free amine groups. See also MPEP 2112.

With respect to claims 27 and 36, the device of Sundberg et al. comprises dimethyl maleic anhydride (Figure 9b). It is noted that although the claims refer to di<u>methyl</u> maleic anhydride, it is understood that this would encompass <u>methylene</u> groups that are formed upon covalent bond formation with the substrate and/or with other molecules. See the instant specification at Figure 1, structures 2-3, where it is apparent that upon reaction of an R1 methyl

group, the resulting group must actually be methylene (or else it would be a 5-bond carbon). As the device of Sundberg et al. also features a maleic anhydride in which the carbons at the 2 and 3 positions are bonded to methylene carbons, this reads on the claim. Further, the poly(ethylene/maleic anhydride) polymer would also read on "derivatives" of diethyl maleic anhydride absent a specific or limiting definition for this term in the instant specification.

With respect to claim 28, Sundberg et al. teach that the solid support contains reactive sites for subsequent covalent attachment (column 10, line 55 to column 12, line 46). See the reactive amine groups on the substrate in Figure 9b, which are subsequently covalently bound to the poly(ethylene/maleic anhydride) polymer.

With respect to claims 31 and 35, Sundberg et al. is silent as to whether the maleic anhydride compound is capable of reversible covalent binding. However, Figure 9b depicts immobilization of the maleic anhydride compound with the two reactive carbonyls exposed to the surface. Because the device of Sundberg et al. therefore also involves accessible carbonyl groups of maleic anhydride compounds, the prior art device appears to be substantially identical to that claimed and is presumed to possess the same properties. See MPEP 2112.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pierce in view of Dean et al. (U.S. 3,904,478).

Pierce is as discussed above, which teaches a device substantially as claimed in which the substrate is polystyrene (see entire selection). The reference differs from the claimed invention in that it fails to teach aminohexyl or aminododecyl agarose as the substrate material.

Dean et al. teach water-insoluble polymeric support materials that can be used for immobilization of biomolecules (co-enzymes). See the abstract and column 1, lines 1-20. Examples of such polymeric supports include polystyrenes, as well as aminohexyl-Sepharose (an agarose). See column 2, lines 42-64.

The teachings of Dean et al. indicate that both polystyrene (as taught by Pierce) as well as aminohexyl-agarose were recognized in the prior art to be functional equivalents suitable for the same purpose, namely as water-insoluble polymeric support materials capable of supporting biomolecule immobilization.

Therefore, it would have been obvious to substitute aminohexyl-agarose as taught by Dean et al. for polystyrene as the support material in the device of Pierce. In particular, substitution of aminohexyl-agarose for polystyrene in the device of Pierce would have been obvious as both of these materials were known to be suitable for fabricating polymeric support materials that can immobilize biomolecules.

18. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sundberg et al. in view of Dean et al.

Sundberg is as discussed above, which teaches a device substantially as claimed. Suitable substrates materials include polystyrene, as well as other substrate materials that contain reactive groups such as amino groups (column 11, lines 20-40). However, the reference differs from the claimed invention in that it fails to teach aminohexyl or aminododecyl agarose as the substrate material.

The teachings of Dean et al., discussed immediately above, indicate that both polystyrene (as taught by Sundberg et al.) as well as aminohexyl-agarose were recognized in the prior art to be functional equivalents suitable for the same purpose, namely as support materials for biomolecule immobilization.

Therefore, it would have been obvious to substitute aminohexyl-agarose as taught by Dean et al. for polystyrene as the support material in the device of Sundberg et al. because these materials were recognized in the prior art to be functional equivalents suitable for the same purpose. Furthermore, it would have been obvious to select aminohexyl-agarose as the substrate material in the device of Sundberg et al. because Sundberg et al. taught that the substrate preferably contains reactive groups such as amino groups. As such, the selection of the known amino reactive group-containing substrate aminohexyl-agarose would have been obvious.

19. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pierce in view of Vuong et al. (U.S. 6,448,089 B1).

Pierce is as discussed above, which teaches a substrate (polystyrene plates, which may be 96-well multiwell plates) but which fails to teach a solid support to which the substrate is bound.

Vuong et al. teach a multiwell plate scanner for measuring samples in wells of a multiwell plate (abstract and column 11, lines 8-32). To use the scanner, a multiwell plate is mounted onto a positioning stage and clamped firmly in place on the plate positioner (see column 7, lines 3-27, and Figure 3).

Therefore, it would have been obvious to one of ordinary skill in the art to clamp the multiwell plates of Pierce to the positioning stage of Vuong et al., thereby binding the polystyrene substrate of Pierce to a solid support. One would be motivated to do this in order to allow for the polystyrene plates to be subsequently scanned with a plate scanner. In particular, since Pierce teaches using their plates for ELISA, one would be motivated to combine the reference teachings in this manner so that upon addition of assay reagents to the plates, the results of the ELISA assays could be detected in an automated manner using a plate scanner.

20. Claims 1-3, 5-9, 25, and 27-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garman et al. ("The preparation and properties of novel reversible polymer-protein conjugates. 2-ω-Methoxypolyethylene (5000) glycoxymethylene-3-methylmaleyl conjugates of plasminogen activators" FEBS Lett. 1987 Nov 2;223(2):361-5) in view of Batista et al. (U.S. 5,807,997).

Garman et al. teach a maleic anhydride compound (2,3-dimethylmaleic anhydride) that is covalently bound through a functional group at the 2 or 3 position of the maleic anhydride to the polymer methoxypolyethylene glycol (see the abstract; Scheme 1; and sections 2.1 and 2.2 in particular. The bound 2,3-dimethylmaleic anhydride contains exposed carbonyl groups that are capable of reversible coupling to proteins, allowing for the polymer to be conjugated to proteins

via the maleic anhydride compound (see page 361, last paragraph to page 362, second paragraph; and Scheme 1 in particular).

The teachings of Garman et al. differ from the claimed invention in that the maleic anhydride compound is bound to a soluble polymer rather than to a substrate having a surface or to a solid support.

Like Garman et al., Batista et al. also relates to covalent conjugates of polymers with reactive compounds (in this case, thiol compounds; abstract and column 1, lines 16-34). The polymers to be conjugated may be either water-soluble or water-insoluble; the latter include chromatography supports such as dextrans, agarose, etc. (column 2, lines 48-62; column 3, lines 16-21; column 5, lines 22-37). Alternatively, water-soluble polymers may be rendered insoluble by being covalently bound to the surface of a support that is insoluble (column 5, lines 22-37). The resulting supports can be used for covalent chromatography involving reversible insolubilization of biomolecules ("bio-active compounds"; see column 5, lines 38-50). Because the maleic anhydride compound reversibly interacts with biomolecules, the chromatography support can be regenerated after use (column 5, lines 51-55).

The teachings of Batista et al. indicate that it was known that reactive compounds can be attached to either water-soluble or water-insoluble polymers, and that reactive compounds attached to the latter may be used as chromatography supports. Although Batista et al. exemplifies a thiol-reactive compound while Garman et al. teaches a maleic anhydride compound, one of ordinary skill in the art would readily appreciate the parallels; in particular, both reactive compounds are covalently attached to polymers for the purpose of subsequently binding biomolecules in a covalent but reversible manner.

Further, Batista et al. teaches that conjugates of water-insoluble polymers are useful for preparing affinity adsorbents that carry a covalently attached reactive compound exhibiting biospecific affinity, which can be used for reversible insolubilization of bio-active compounds by covalent chromatography.

It would have been obvious to one of ordinary skill in the art to modify the teachings of Garman et al. by attaching the maleic anhydride compound to a polymer that is water-insoluble rather than water-soluble. In particular, it would have been obvious to attach 2,3-dimethylmaleic anhydride to a water-insoluble polymer such as agarose or dextran rather than to the water-soluble methoxypolyethylene glycol polymer exemplified by Garman et al. Alternatively, based on the teachings of Batista et al. that water-soluble polymers may be rendered insoluble by being covalently bound to the surface of a support that is insoluble, such as a chromatography support, it would have been obvious to attach 2,3-dimethylmaleic anhydride to a water-soluble polymer (e.g., methoxypolyethylene glycol) that is itself covalently attached to the surface of a solid chromatography support.

Motivation to combine the reference teachings in this manner comes from the teachings of Batista et al., which indicate that it was known in the prior art to prepare conjugates of reactive compounds with both water-soluble and water-insoluble polymers. Batista et al. teach that the conjugates involving the latter are useful as chromatography supports for reversible covalent chromatography. Consequently, one would be motivated to attach the maleic anhydride reactive compound of Garman et al. to a water-insoluble polymer so as to prepare a chromatography support that could be used for reversible covalent chromatography of proteins. Put another way, although Garman et al. only apparently contemplated using the maleic

anhydride-polymer conjugates for *in vivo* use, it would have been obvious to modify the teachings of Garman et al. in order to be able to use the conjugates in other applications for which reactive polymer conjugates were known to be useful.

With respect to claim 3, Batista et al. teach suitable water-insoluble polymers for use as chromatography supports, including agarose (column 5, lines 30-37).

With respect to claims 8-9, Garman et al. teach that the polymer-protein conjugates react with amino groups on proteins (see title and page 362, left column). Consequently, when employing water-insoluble polymers in the device of Garman et al. and Batista et al., it would necessarily follow that the maleic anhydride compound would be capable of binding amine-containing biomolecules including proteins.

With respect to the recitations that reversible covalent binding occurs under selected pH conditions and/or within a given time period, since 2,3-dimethylmaleic anhydride is also disclosed in the instant specification as a suitable maleic anhydride compound (see page 8, line 10), it is presumed that the 2,3-dimethylmaleic anhydride-containing device of Garman et al. and Batista et al. would necessarily possess the same properties, e.g. reversibility in less than 1 hour.

21. Claims 4 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garman et al. in view of Batista et al. as applied to claims 1 and 25 above, and further in view of Dean et al.

Garman et al. and Batista et al. are as discussed above, which teaches a device substantially as claimed. Batista et al. teaches that suitable water-insoluble polymers for use as

chromatography supports include agarose, dextran, and polyacrylamide (column 5, lines 30-36). However, the references fail to specifically teach *aminohexyl* or *aminododecyl* agarose.

Dean et al. (discussed above) teaches insoluble support materials for immobilizing biomolecules. In particular, Dean et al. teach that known support materials include dextran, polyacrylamide, agarose, and aminohexyl agarose. See column 2, lines 42-64.

The teachings of Dean et al. indicate that agarose, dextran, and polyacrylamide (as also taught by Batista et al.) as well as aminohexyl-agarose were recognized in the prior art to be functional equivalents suitable for the same purpose, namely as support materials for biomolecule immobilization.

Therefore, it would have been obvious to substitute aminohexyl-agarose as taught by Dean et al. for agarose, dextran or polyacrylamide as the support material in the device of Garman et al. and Batista et al. because these materials were recognized in the prior art to be functional equivalents suitable for the same purpose.

Response to Arguments

22. Applicant's arguments in the Reply filed 12/20/2007 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571) 272-8786. The examiner can normally be reached on M-F 6:30-3:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, can be reached at (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christine Foster/
Examiner, Art Unit 1641